

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES



In the Matter of
GEMTRONICS, INC.,
a corporation, and
WILLIAM H. "BILL" ISELY,
individually and as the owner
of Gemtronics, Inc.

DOCKET No. 9330

Public Document

COMPLAINT COUNSEL'S MOTION FOR SUMMARY DECISION

Pursuant to Section 3.24 of the Commission's Rules of Practice, Complaint Counsel moves for summary decision in this matter. Based on the pleadings and other evidence in this case, as described in Complaint Counsel's Statement of Material Facts as to Which There is No Genuine Dispute, Complaint Counsel is entitled to summary decision as to violations of Sections 5(a) and 12 of the Federal Trade Commission Act. The arguments supporting Complaint Counsel's motion are set forth in the accompanying Memorandum in Support of Complaint Counsel's Motion for Summary Decision.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Barbara E. Bolton", written over a horizontal line.

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Federal Trade Commission
225 Peachtree Street, Suite 1500
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Dated: March 16, 2009

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**COMPLAINT COUNSEL'S MEMORANDUM IN SUPPORT OF
MOTION FOR SUMMARY DECISION**

I. INTRODUCTION

Complaint Counsel moves for Summary Decision, pursuant to Commission Rule of Practice 3.24, against Respondents Gemtronics, Inc. ("Gemtronics"), and William H. Isely ("Isely"), individually and as the owner of Gemtronics. The Federal Trade Commission ("FTC") issued its Complaint in this matter on September 18, 2008, alleging that Respondents violated Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act") by making false and unsubstantiated claims that the product, RAAX11, a food or drug within the meaning of Sections 12 and 15 of the FTC Act, is effective in preventing, treating, or curing various types of cancer and that these claims are proven by reliable scientific evidence.

The uncontroverted evidence presented herein reveals that Respondents made false and unsubstantiated cancer claims in Internet advertisements that deceived consumers nationwide about the about the benefits of RAAX11. The evidence presented also clearly demonstrates that scientific evidence does not support any cancer-related claims for RAAX11 and that

Respondents did not possess adequate substantiation for their claims.

Summary decision is appropriate in this case because the evidence demonstrates that Respondents made the alleged claims, in violation of Section 5(a) and 12 of the FTC Act. There is no genuine issue of material fact as to whether Respondents made the representations challenged in the Commission's Complaint, or as to whether such representations are false and unsubstantiated.

Complaint Counsel seeks a proposed order that, among other things, 1) enjoins Respondents from making or assisting others in making false, misleading, or unsupported claims in connection with the marketing of RAAX11 and other health-related products, and 2) requires Respondents to notify their customers who purchased RAAX11 that scientific studies do not demonstrate that RAAX11, or its ingredients, are effective in the treatment of cancer.

II. STATEMENT OF FACTS¹

A. Respondents' Business

Starting in at least 2004, Respondent Isely was operating a business from his residence that advertised and sold dietary supplements to consumers nationwide through mail order, telephone, and the Internet. (CCSF ¶¶ 3, 4.) He ran this business as a sole proprietor under the assumed name Gemtronics. (CCSF ¶ 3.) In September 2006, Isely incorporated Gemtronics, Inc., a North Carolina corporation, whose principal place of business is located in Franklin, North Carolina, at Isely's residence. (CCSF ¶¶ 1, 4.) Respondent Isely is the owner, registered agent, and general manager of Gemtronics (CCSF ¶ 5.) After incorporating Gemtronics, Isely

¹ Pursuant to Rule of Practice § 3.24(a), Complaint Counsel has submitted the accompanying Statement of Material Facts As To Which There Is No Genuine Issue ("CCSF") as a separate document.

continued his business advertising and selling dietary supplements through this corporate entity. (CCSF ¶18.)

Since 2004, Respondent Isely and, since 2006, Respondent Gemtronics have advertised and sold the dietary supplement RAAX11 to consumers nationwide through mail order, telephone, and Internet websites, including, *inter alia*, the website www.agaricus.net. (CCSF ¶19.) Since at least 2006, Respondent Isely's name, address and telephone number have been listed in the Internet domain registration for the domain "agaricus.net" as the domain's registrar and its administrative and technical contact. (CCSF ¶ 20.) From 2004 through 2008, Respondents sold approximately 1150 bottles of RAAX11 at a cost of approximately \$120 per bottle. (CCSF ¶21.) Respondents charged shipping and handling fees of \$15.00. (CCSF ¶ 22)

B. Respondents' Deceptive Advertising Claims for RAAX11

Through the website advertising claims, listed below, found on www.agaricus.net, as well as other claims found elsewhere in the website, Respondents have made both express and implied representations that RAAX11 is effective and/or is scientifically proven to be effective in preventing, treating or curing various types of cancer.

1. Claims that RAAX11 is scientifically proven effective as a treatment or cure of various types of cancer, including but not limited to leukemia, and cancers of the breast, brain, lung, bowel, larynx, and pancreas

Two webpages found on www.agaricus.net contain similar representations that RAAX11 has been proven effective as a treatment or cure of "human cancers," including, but not limited to leukemia, and cancers of the breast, brain, lung, bowel, larynx, and pancreas:

**Has a cancer killer been discovered?
RAAX11 Extract . . .**

Brazilian scientists have discovered a tropical plant substance that holds great promise in the fight against various types of cancer. . . .

Scientists report that during laboratory tests the substance destroyed cancer cells that had been resistant to treatment up to now. This is a rare occurrence. This substance is so promising it is being kept under wraps at present.

(CCSF ¶ 9.)

Even very resistant Leukemia cells die off

The successful lab tests were carried out on cells from breast- brain- lung- bowel- larynx- and pancreas tumors. “What has been most surprising to us, is the fact that besides these cancer cells, leukemia cells that are normally resistant to a lot of medicines and methods of treatment, were also killed” reported the scientists. It was initially questioned whether the substance, obtained from the Chrysobalanus Icaco plant was suited for the treatment of human cancers, but the results showed that it worked with 90% of the patients.

(CCSF ¶ 7.)

In addition to the representation regarding breast cancer, above, another webpage on the website contains the claim that RAAX11 has been scientifically proven effective in treating or curing breast cancer:

Breast Cancer Patients in remission (2006) 621 out of 749 People
in remission taking the RAAX11 protocol

* * *

**RAAX11 Offers New Hope for an
Alternative Breast Cancer Treatment**

In a recent study, 91 women who were suffering from breast cancer at stage IIIb or IV took part in our RAAX11 protocol. By April 2004, 41 women had totally recovered, 23 women were in remission, 27 were stable, and only 9 had not survived, a survival rate of 91.27%.

(CCFS ¶ 9.)

A fourth webpage on www.agaricus.net contains a representation that RAAX11 is effective in treating leukemia:

B-Cell Chronic Lymphocytic Leukemia

Patient, m, 54, in remission taking the RAAX11 protocol.
(CCSF ¶ 9.)

2. Claim that RAAX11 is scientifically proven effective in preventing cancer, including but not limited, to uterine cancer

Beneath the webpage representations, noted above in Section II.B.1., that “scientists have discovered a tropical plant substance” found to be effective in “during laboratory tests,” the claim is made in that “ABM” (*agaricus blazei murill* mushrooms), one of the two ingredients in RAAX11, has been proven effective in the prevention of cancer, particularly uterine cancer:

Anti cancer effect: ABM contains natural steroids, known for it’s anti cancer effect. . . . It is particularly effective in prevention of uteran cancer.
(CCSF ¶ 9.)

III. NO SCIENTIFIC EVIDENCE SUPPORTS THE RAAX11 CANCER CLAIMS

In support of its Motion for Summary Decision, Complaint Counsel submits the Expert Report of Dr. Omer Kucuk, an expert in the fields of cancer research and treatment, and in the use of botanical compounds on cancer patients. (CCSF ¶ 23.) Dr. Kucuk is Board Certified in Medical Oncology with the American Board of Internal Medicine. (CCSF ¶ 24.) Dr. Kucuk has been a practicing in the field of medical oncology for over 27 years. (CCSF ¶ 24.) His areas of expertise include cancer prevention, nutrition and cancer, chemoprevention, chemotherapy, medical oncology and clinical trials. (CCSF ¶ 24.) Dr. Kucuk conducts clinical research treating cancers of the prostate, bladder, kidney and testis. (CCSF ¶ 25.) He has authored or co-authored approximately 125 articles published in peer-reviewed scientific journals and more than 20 published book chapters and reviews. (CCSF ¶ 26.)

In his report, Dr. Kucuk states that cancer is not a single disease but many different diseases, and there is no known treatment that is generally accepted as effective for all forms of

cancer. (CCSF¶ 27.) According to Dr. Kucuk, to support cancer treatment claims for a product, qualified experts in the field of oncology would require such claims to be supported by well-conducted, placebo-controlled, randomized, double-blind, clinical trials demonstrating the product's efficacy for the specific type(s) of cancer for which the claims are made. (CCSF¶ 28.)

Dr. Kucuk's report details his review of the RAAX11 product label, the documents submitted by Respondents as substantiation for the RAXX11 product claims, and his own independent search of the existing scientific literature. (CCSF¶ 29.) After completing his review, Dr. Kucuk's expert opinion is that the existing body of scientific literature does not provide competent and reliable evidence that RAAX11, or either of its ingredients *Chrysobalanus icaco* ("icaco") and *Agaricus blazei murill* ("agaricus"), alone or in combination, has been scientifically proven to, or effectively can prevent, treat or cure any form of cancer. (CCSF¶ 30.)

A. No Scientific Evidence on RAAX11 or Its Ingredients on Cancer Patients

According to his expert report, Dr. Kucuk found no published scientific literature evaluating either RAAX11 or evaluating the combination of *icaco* and *agaricus* as a cancer treatment. (CCSF¶ 31.) Specifically, Dr. Kucuk reported finding no published scientific literature evaluating the efficacy of RAAX11 or any clinical trial data with RAAX11. (CCSF¶ 32.) Further, Dr. Kucuk's search of the published scientific literature revealed no articles about the efficacy of taking the combination of *icaco* and *agaricus* as a cancer treatment, or even looking at potential mechanisms of anticancer activity. (CCSF¶ 33.) In examining the ingredients in RAAX11 separately, Dr. Kucuk found no published studies that evaluate *icaco* extract as a cancer treatment nor did he find a single human or animal study of *icaco*. (CCSF¶ 34.) While Dr. Kucuk's report states that he found eight publications reporting the results of

clinical or human studies using *agaricus*, he found no reports of properly conducted clinical trials regarding the efficacy of *agaricus* extract in patients with cancer. (CCSF ¶ 35.)

Further, specifically evaluating the scientific literature in light of the allegations contained in the Commission's Complaint, Dr. Kucuk concluded that there is no scientific support for the claims that: (1) reliable scientific evidence demonstrates that RAAX11 is effective in the prevention, treatment, and cure of cancer (Complaint ¶ 6); (2) RAAX11 is effective in the treatment and cure of various types of cancer, including, but not limited to leukemia and cancers of the breast, brain, lung, larynx, pancreas, and bowel (Complaint ¶ 8.A.); and (3) RAAX11 is effective in the prevention of cancer, including, but not limited to uterine cancer (Complaint ¶ 8.B.). (CCSF ¶ 36.)

B. Respondents Provided No Competent and Reliable Evidence to Support the Claims for RAAX11

Respondents submitted three articles downloaded from the Memorial Sloan Kettering database regarding *agaricus* which were analyzed by Dr. Kucuk in his report. After reviewing the materials, it is Dr. Kucuk's conclusion that the materials do not provide any data from randomized, placebo-controlled clinical trials with cancer patients and therefore, they do not provide any additional relevant clinical data to substantiate or otherwise support the cancer claims challenged in the Commission's Complaint for RAAX11. (CCSF ¶ 50.)

IV. RESPONDENTS HAVE VIOLATED SECTION 5 AND 12 OF THE FTC ACT

A. Respondents' Advertising Claims are Facially Clear and Material

An advertisement is deceptive if it contains a representation or omission of fact that is likely to mislead consumers acting reasonably under the circumstances, and that representation or omission is material to consumers' purchasing decisions. *FTC Policy Statement on*

Deception, 103 F.T.C. 174, 175 (1984) (Deception Statement); *see, e.g., Telebrands Corp.*, 140 F.T.C. 279, 290 (2005); *Novartis Corp.*, 127 F.T.C. 580, 679 (1999), *aff'd*, 223 F.3d 783 (D.C. Cir. 2000); *Stouffer Foods Corp.*, 118 F.T.C. 746, 798 (1994); *Kraft, Inc.*, 114 F.T.C. 40, 120 (1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993). Advertising claims are also presumed to be material if they are express or if they pertain to the purpose, safety, or efficacy of the product. *Deception Statement*, 103 F.T.C. at 182, *see, e.g., Telebrands Corp.*, 140 F.T.C. 379, 450 (Initial Decision 2004).

The *prima facie* evidence of what representations an advertisement conveys to reasonable consumers is the advertisement itself. *Deception Statement*, 103 F.T.C. at 176; *see, e.g., Telebrands Corp.*, 140 F.T.C. at 290; *Novartis*, 127 F.T.C. at 680; *Stouffer*, 118 F.T.C. at 798; *Kraft*, 114 F.T.C. at 121. When the language of an advertisement is clear enough to permit the Commission to conclude with confidence that the ad can reasonably be read to contain a particular claim, a facial analysis, alone, will permit the Commission to conclude that the ad contains the claim. *Stouffer Foods Corp.*, 118 F.T.C. 746, 798, *citing Kraft, supra*, at 121 and *Thompson Medical Co.*, 104 F.T.C. 648, at 789 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987). Thus, where the language in the challenged advertisement is clear, the Commission may rely on the ad itself and need not resort to extrinsic evidence to determine if the claim is conveyed to reasonable consumers. *Novartis*, 127 F.T.C. at 680; *see Stouffer*, 118 F.T.C. at 798; *Deception Statement*, 103 F.T.C. at 176.

Applying this standard, claims made in Respondent's advertisements highlighted are clear on their face. Therefore, there is no requirement for extrinsic evidence to determine if these claims are conveyed to reasonable consumers. In fact, Respondents have not contested that the

claims were made. (Answer ¶ 5.) Respondents' advertising claims are also material, not only because they are express, but also because they relate to the purpose, safety, and/or efficacy of RAAX11, a product advertised specifically as a cancer prevention, treatment and cure. *See, e.g., Deception Statement*, 103 F.T.C. at 182.

B. Respondents' Claims are False and Unsubstantiated

The Commission has consistently held that objective claims made without a reasonable basis constitute a deceptive practice in violation of Section 5. *FTC Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. 839 (1984) (*Substantiation Statement*); *see, e.g., Automotive Breakthrough Sciences, Inc.*, 126 F.T.C. 229, 293 & 293 n.20 (1998); *Jay Norris, Inc.*, 91 F.T.C. 751, 854 (1978), *aff'd as modified*, 598 F.2d 1244 (2d Cir. 1979), *cert. denied*, 444 U.S. 980 (1979). What constitutes a reasonable basis is an objective standard: advertisers must possess at least the level of substantiation expressly or impliedly claimed in the advertisement. *See Honeywell, Inc.*, 126 F.T.C. 202 (1998); *FTC v. Natural Solution, Inc.*, No. CV 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at *10 (C.D. Cal. Aug. 7, 2007) (citing *FTC v. U.S. Sales Corp.*, 785 F. Supp. 737, 748 (N.D. Ill. 1992)).

For health and safety claims, advertisers must possess competent and reliable scientific evidence substantiating their claims in order to have a reasonable basis for such claims. *See FTC v. National Urological Group, Inc.*, No. 1:04-CV-3294-CAP, 2008 U.S. Dist. LEXIS 44145, at *77 (N.D. Ga. June 4, 2008) (granting FTC's summary judgment motion, court finds safety and efficacy claims for dietary supplements must be substantiated by competent and reliable scientific evidence); *Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *11-13 (granting FTC's summary judgment motion, court requires competent and reliable scientific evidence for cancer prevention and treatment claims for product); *FTC v. QT, Inc.*, 448 F. Supp.

2d 908, 961 (N.D. Ill. 2006) *aff'd*, 512 F.3d 858 (competent and reliable scientific standard applied for evidence that bracelet relieves pain). Competent and reliable scientific evidence is typically defined as tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results. *See, e.g., Brake Guard Products, Inc.*, 125 F.T.C. 138 (1998); *ABS Tech Sciences, Inc.*, 126 F.T.C. 229 (1998).

To provide adequate substantiation to support the truthfulness of health-related efficacy claims, courts have consistently required double-blind, placebo-controlled studies. *See, e.g., FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263, 1274 (S.D. Fla. 1999) (double-blind study of the combination of product's ingredients required to support product claims); *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1008-09 (N.D. Ill. 1998) (study found not valid as substantiation, in part, because neither blinded nor placebo controlled); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 962 (medical claims for bracelet required a well-conducted, placebo-controlled, randomized, double-blind study).

The product at issue in this case, RAAX11, is dietary supplement that is advertised and sold as a cancer treatment, prevention and cure. Respondents' advertising representations relate to health and safety and, thus, require substantiation consisting of competent and reliable scientific evidence. As noted above, Complaint Counsel's expert, Dr. Kucuk concludes that to support cancer treatment claims for a product, qualified experts in the field of oncology require randomized, well-controlled, and double-blinded clinical trials demonstrating a product's efficacy for the specific type(s) of cancer for which the claims are made. After examining the substantiation submitted by Respondents, as well as examining the current state of peer-reviewed scientific literature regarding RAAX11 and its ingredients, it is Dr. Kucuk's expert opinion that

